K093250

510(k) Summary

The information below is provided for the Varian Medical Systems Proton Therapy Multileaf Collimator following the format of 21 CFR 807.92.

1. Submitter:

Varian Medical Systems
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Palo Alto, CA 94304
Contact Name: Vy Tran
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DEC 2 4 2009

2. Name of the Device: Proton Therapy Multileaf Collimator
   Trade / Proprietary Names: iPTMLC ; Proton Therapy Multileaf Collimator; Proton Multileaf Collimator; Proton MLC
   Common or Usual Name: Accessory to Proton Therapy System
   Classification Name: Medical Charged Particle Radiation Therapy System
   21 CFR §892.5050
   Class II
   Product Code: LHN

3. Predicate Device to claim substantial equivalence:
   Varian Medical Systems Millennium Multileaf Collimator – K050442

4. Description of the Device:

   The Varian Proton Therapy Multileaf Collimator is an accessory proton beam collimator designed to be mounted on a proton radiation therapy system and is designed to shape the treatment field perimeter.

   The Proton Therapy Multileaf Collimator is designed to shape a proton beam for cancer treatment. There are two operating modes:

   a. Pencil Beam Scanning (PBS) where proton therapy equipment nozzle scanning magnets direct the proton beam to the voxel of treatment while the Proton Therapy Multileaf Collimator is parked with the carriage fully retracted for largest possible exposure field.

   b. Beam Shaping where the Proton Therapy Multileaf Collimator collimates the beam for treatment, replacing the current patient-customized final collimator. This Proton Therapy Multileaf Collimator mode of operating is used for double and single scattering and uniform scanning proton treatment modes.

5. Intended Use Statement

   The Varian Proton Therapy Multileaf Collimator is an accessory radiation collimator intended to assist the radiation oncologist in the delivery of proton radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

6. Indications for Use Statement

The Varian Proton Therapy Multileaf Collimator is an accessory radiation collimator intended to assist the radiation oncologist in the delivery of proton radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

7. Substantial Equivalence

The Varian Medical Systems Proton Therapy Multileaf Collimator submission illustrates substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Vice President Corporate Regulatory Affairs
Varian Medical Systems
3100 Hansen Way
PALO ALTO CA 94304-1038

DEC 24 2009

Re: K093250
Trade/Device Name: Proton Therapy Multileaf Collimator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: October 14, 2009
Received: October 16, 2009

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K093256

Device Name: Proton Therapy Multileaf Collimator

Indications for Use:

The Varian Proton Therapy Multileaf Collimator is an accessory radiation collimator intended to assist the radiation oncologist in the delivery of proton radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X_____ OR Over-the-counter _____
(Per 21 CFR § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093250